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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,743	02/19/2004	Hideyuki Yanami	KAS-199	1792

24956 7590 04/18/2007
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ALEXANDRIA, VA 22314

EXAMINER

BEX, PATRICIA K

ART UNIT	PAPER NUMBER
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1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/780,743

Applicant(s)

YANAMI ET AL.

Examiner

P. Kathryn Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement filed October 07, 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it does not provide a translation of reference no EPO 601213, which is in a non-English language (German). Nor does the specification discuss the relevance of the aforementioned reference. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Specifically, the "mechanism capable of changing the arrangement of said plurality of sample containers" recited in

claim 1, line 4, must be shown. While the specification teaches the use of a rack 11 for transporting/housing sample containers 10, there is no element capable of *changing the arrangement of the sample containers*.

Moreover, the "sample container loading mechanism" recited in claim 1, must be clearly depicted in the figures. The specification does state the sample container loading mechanism may include a sample disk (see penultimate paragraph, page 4). The instant drawings do not illustrate a disk. Rather, the samples containers are moved along a conveyer mechanism 12. Thus, the Detailed Description section should recite the "sample container loading mechanism" including a corresponding to a reference character that can be found in the Figures.

Similarly, the "reaction cuvette loading mechanism" recited in claim 1, must be clearly depicted in the figures. The specification does teach the reaction cuvette loading mechanism may be in the form of a reaction disk, or structure capable of linearly moving the reaction cuvettes (see beginning at penultimate paragraph at page 4). However, the Detailed Description section should recite the "reaction cuvette loading mechanism" with corresponding to a reference character.

Claim 2 recites, "a mechanism for enabling said plurality of nozzles being vertically movable independently of each other". This mechanism must be shown in the Figures. For the purpose of Examination the Office has interpreted this mechanism as the "drive source" described at page 12, penultimate paragraph. Similarly, the "fixed track" recited in claims 2-3 must be shown.

Claim 5, recites a "liquid level detecting function of detecting a surface level of the sample in said sample container". Claim 6, recites a "nozzle clogging function of detecting clogging of the relevant nozzle". Neither of these claimed features are illustrated in any of the Figures.

All of the aforementioned elements must be shown or canceled from the claims.
No new matter should be entered.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "62" has been used to designate both what appears to be the analyzer (see Fig. 1) and the reaction cuvette (see Figs. 3, 5, 7-8).

5. The drawings are also objected to because reference characters "62" and "35" have both been used to designate the "reaction cuvette", see for example page 10 and page 12.

6. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities: SUMMARY OF INVENTION on page 2 is misspelled. Appropriate correction is required.

8. The specification is further objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: “mechanism capable of changing the arrangement of said plurality of sample containers”, as recited in claim 1, should find basis in the specification.

Also, the “reaction cuvette loading mechanism” recited in claim 1, must also find basis in the specification. The limitation should include a corresponding reference character in the Figures.

Similarly, claim 2 recites “a mechanism for enabling said plurality of nozzles being vertically movable independently of each other”; this limitation must find basis in the specification. The Office believes this mechanism corresponds to the drive source described, but not shown, see page 12, penultimate paragraph.

Also the “fixed track” in both claims 2 and 3 must find basis in the specification. The Office believes the “fixed track” corresponds to the “rails 71, 73” described at page 12, penultimate paragraph, however clarification is required.

Claim Rejections - 35 USC § 112

9. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim 1, recites the “mechanism capable of changing the arrangement of said sample containers”. It is indefinite what element is capable of changing the arrangement of the sample containers in the claimed apparatus? Furthermore, the specification and figures do not provide support for this mechanism. Thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 4, recites “wherein said particular position for sucking the sample is provided in plural”. It is not clear what Applicant is referring to by this limitation. The specification, states at page 7, line 13 from bottom, that each of the sample dispensing mechanisms may be provided with any other suitable moving means so that the sample dispensing mechanism can be moved to a desired one of plural sample suction positions and desired one of plural positions on the reaction disk. For examination purposes, this limitation has been interpreted to mean one of plural sample suction positions. However, clarification by Applicant is required.

Claim 8 is indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Babson et al. (US Patent no. 5,885,530), hereinafter Babson.

Babson teaches an analyzer system 10 including the sample dispensing apparatus as currently claimed. The apparatus comprises a container loading mechanism (racks) "capable of" loading a plurality of containers and including a mechanism (carousels 207, 209) capable of changing the arrangement of the plurality of containers via rotation (see col. 5, lines 55; Figs. 2A-2B). The sample container loading mechanism of Babson is in the form of a disk, or carousel, like that disclosed in the present invention at page 4.

Additionally, Babson teaches a reaction cuvette loading mechanism 201, 202, 213, 215 "capable of" loading and moving a plurality of reaction cuvettes 840 throughout the system (see col. 5, line 1+). This reaction cuvette loading mechanism includes a series of conveyers 201, 202, 213, 215 which read on the "mechanism 'capable of' changing arrangement of plurality of the reaction cuvettes" (i.e., plunger not shown; see col. 5, lines 50-54). The Babson analyzer is designed to change the original

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arrangement of the reaction cuvettes based on the timing of the incubation, mixing, washing, and detection operations for a particular cuvette.

Furthermore, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Babson teaches a fluid dispensing mechanism for aspirating the sample from the sample container at a particular location in the carousel and discharging the aspirate into the reaction cuvette at station 204. The sample dispensing apparatus includes a plurality of nozzles 205, 206 for aspirating and discharging the fluid. The plurality of nozzles being vertically movable to aspirate and discharge the fluid independently of each other. The dispensing apparatus of Babson also includes mechanisms capable of rotating the nozzles between the sample container and the reaction cuvette independently of each other (see col. 6, line 13- col. 7, line 42).

Please note that Babson teaches one of the plurality of nozzles 205 for sample and the other nozzle 206 for dispensing reagent. Babson does not teach both nozzles for dispensing sample, however, the material or article worked upon (i.e., sample) does not limit an apparatus claim but is rather an intended use of the apparatus. Thus, the claimed apparatus does not differentiate from a prior art apparatus since the prior art apparatus teaches all the structural limitations of the claim. See MPEP 2114 and 2115 and *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

With respect to claim 5, Babson teaches at least one nozzle 206 having a liquid level detecting function for detecting the surface level of the fluid in the container (see col. 6, lines 20-25.)

Babson also teaches a clot detection apparatus (see col. 6, lines 41-46). Clots naturally agglomerate. This can result in clogs in the flow passage of the nozzle. Thus, the clot detecting apparatus of Babson is capable of detecting clogs therein.

With respect to claim 7, the analyzer system of Babson includes a computer 12 that controls the nozzles individually. That is, if one nozzle is detected as being situated over the reaction cuvette at station 204, the other nozzle will wait (stop) for the other nozzle to clear the reaction tube before swiveling over the mouth of the cuvette to deposit its contribution to the cuvette (see col. 7, lines 30-39).

12. Claims 1-2, 4 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Itoh (US Patent no. 5,445,037).

Itoh teaches the sample dispensing apparatus substantially as claimed. The Itoh apparatus comprises a sample container loading mechanism (not shown; see col. 4, lines 11+) "capable of" loading a plurality of sample containers 10. Furthermore, the series of conveyers 41, 42 are capable changing the arrangement of the plurality of containers. Itoh also teaches a reaction cuvette loading mechanism (not shown; see col. 5, lines 57+) "capable of" loading and moving a plurality of reaction cuvettes 20 throughout the system. The reaction cuvette loading mechanism includes a series of conveyers 43, 45 and transport direction changeover unit 140 which read on the "mechanism 'capable of' changing arrangement of plurality of the reaction cuvettes".

Furthermore, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Itoh teaches a fluid dispensing mechanism 30 for aspirating sample from the sample container at a particular location and discharging the aspirate into the reaction cuvette at 21T (see col. 8, line 62+). The sample dispensing apparatus includes a plurality of nozzles 33, 39 for aspirating and discharging the sample. The plurality of nozzles being vertically movable to aspirate and discharge the sample independently of each other.

Regarding claim 2, Itoh teaches each of the nozzles being independently movable relative to each other vertically. Furthermore, the nozzles 33, 39 move along a fixed track 31 and 37, respectively (see col. 3, lines 5-67). The independent operation of the Itoh nozzles allows them to aspirate or dispense at one location, as recited in claim 2.

With respect to claim 7, the analyzer system of Itoh includes a controller 100 which controls the nozzles individually (see col. 6, line 62+).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh (US Patent no. 5,445,037).

The teachings of Itoh have been summarized previously, *supra*. The system of Itoh includes, *inter alia*, a fluid dispensing mechanism 30 having a plurality of nozzles 33, 39 for aspirating and discharging the sample. The plurality of nozzles being vertically movable to aspirate and discharge the sample independently of each other. The nozzles 33, 39 move along a fixed track 31 and 37 which is closed at either end by support member (see Fig. 1 and col. 3, lines 5-67).

The fixed track of Itoh is not in the form of a closed loop having an elliptic shape. However, it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the fixed track of Itoh into the form of closed loop since one of the independently controlled nozzles may be moved to opposite sides of the loop should the other nozzle stop working. This reduces labor since the working probe does not have to be removed and remounted on the opposite track.

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Conclusion

16. No claims allowed.


17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

April 14, 2007

pkw


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